K092073

8 **510(k) Summary**

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510(k) Summary	
Submitter:	Thomas Hoghaug, President Signus Medical LLC 18888 Lake Drive East Chanhassen, MN 55317
Contact Person:	Thomas Hoghaug, President Signus Medical LLC 18888 Lake Drive East Chanhassen, MN 55317 Phone: (952) 294-8700
Date Prepared:	July 7, 2009
Trade Name:	MonoPoly Pedicle Screw System
Classification:	888.3050 (spinal interlaminal fixation orthosis and 888.3070 (pedicle screw spinal system)
Product Codes:	NKB, KWP, MNH, MNI. NKB is Class 3; KWP, MNH, and MNI are Class 2.
Predicate Device:	MonoPoly Pedicle Screw System
Device Description:	The MonoPoly Pedicle Screw System is comprised of a variety of monoaxial and polyaxial pedicle screws sizes, couplers, a set screw, cross links, a washer, rods and hooks. All implantable components are manufactured from medical grade titanium alloy (Ti6Al4V-Eli). This premarket notification addresses the introduction of cannulated versions of the MonoPoly pedicle screw component of the system.

510(k) Summary	
Intended Use:	The MonoPoly Pedicle Screw system is intended to help provide immobilization and stabilization of the spinal segments as an adjunct to fusion in skeletally mature patients of the thoracic, lumbar and/or sacral spine (T1-S1), specifically as follows: When used as a pedicle screw fixation system of the non-cervical posterior spine in skeletally mature patients, the MonoPoly Pedicle Screw System is indicated for one or more of the following: (1) degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) (2) degenerative spondylolisthesis with objective evidence of neurologic impairment, (3) fracture, (4) dislocation, (5) spinal tumor, and/or (6) failed previous fusion (pseudarthrosis). When used as a non-cervical and non-pedicle screw fixation system, the MonoPoly Pedicle Screw System is intended for the following indications: (1) degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), (2) spinal stenosis, (3) spondylolisthesis, (4) trauma (fracture, dislocation), (5) pseudarthrosis, (6) tumor resection and/or (7) failed previous fusion.
Functional and Safety Testing:	Mechanical properties were evaluated as per ASTM F1717-04.
Conclusion:	The modification to the original device does not adversely affect performance and the modified device is substantially equivalent to the unmodified predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Signus Medical, LLC
% Mr. Thomas Hoghaug
President
18888 Lake Drive East
Chanhassen, Minnesota 55317

AUG 07 2009

Re: K092073
Trade/Device Name: MonoPoly Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: III
Product Code: NKB, MNI, MNH, KQP
Dated: July 7, 2009
Received: July 8, 2009

Dear Mr. Hoghaug

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

7 Indications for Use

510(k) Number (if known): K092073

Device Name: MonoPoly Pedicle Screw System

Indications For Use:

The MonoPoly Pedicle Screw system is intended to help provide immobilization and stabilization of the spinal segments as an adjunct to fusion in skeletally mature patients of the thoracic, lumbar and/or sacral spine (T1-S1), specifically as follows:

When used as a pedicle screw fixation system of the non-cervical posterior spine in skeletally mature patients, the MonoPoly Pedicle Screw System is indicated for one or more of the following: (1) degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) (2) degenerative spondylolisthesis with objective evidence of neurologic impairment, (3) fracture, (4) dislocation, (5) spinal tumor, and/or (6) failed previous fusion (pseudarthrosis).

When used as a non-cervical and non-pedicle screw fixation system, the MonoPoly Pedicle Screw System is intended for the following indications: (1) degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), (2) spinal stenosis, (3) spondylolisthesis, (4) trauma (fracture, dislocation), (5) pseudarthrosis, (6) tumor resection and/or (7) failed previous fusion.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092073